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BAKER & DANIELS LLP 300 NORTH MERIDIAN STREET SUITE 2700 INDIANAPOLIS, IN 46204			LUCHEISL, NICHOLAS D	
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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* ELDON H. NYHART, JR.

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Appeal 2008-6231  
Application 10/045,550  
Technology Center 3700

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Decided:<sup>1</sup> March 9, 2009

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Before TONI R. SCHEINER, LORA M. GREEN, and  
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the  
Examiner's final rejection of claims 57-65 and 104-106.<sup>2</sup> We have  
jurisdiction under 35 U.S.C. § 6(b).

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<sup>1</sup> The two-month time period for filing an appeal or commencing a civil  
action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date  
shown on this page of the decision. The time period does not run from the  
Mail Date (paper delivery) or Notification Date (electronic delivery).

### STATEMENT OF THE CASE

The claims are directed to a method of delivering a compound. Claim 57 is the only independent claim on appeal, and reads as follows:

57. A method for providing a compound to a system comprising:  
providing a compound releasably captured within a matrix material,  
the compound being releasable upon receiving an energy input, a source of  
energy, and a controller operatively connected to the source and using a  
control signal to operate the source;  
preparing a control signal using fractal mathematics;  
placing the matrix material and captured compound in fluid  
communication with the system; and  
operating the controller with the control signal and providing energy  
to the matrix material sufficient to release a portion of the compound into the  
system.

The Examiner relies on the following evidence:

Altman	US 6,086,582	July 11, 2000
Chupakhin	US 6,028,068	Feb. 22, 2000
Donatsch	US 4,789,673	Dec. 6, 1988
Ellinwood, Jr.	US 4,146,029	Mar. 27, 1979

We reverse.

### ISSUE

The Examiner finds that claims 57-59, 62, 64, 105, and 106 are anticipated by Altman.

Appellant contends that Altman does not inherently teach a fractal based control signal.

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<sup>2</sup> Claims 107-140 are also pending, but stand withdrawn from consideration (App. Br. 1).

Thus, the issue on Appeal is: Has the Examiner established by a preponderance of the evidence that the control signal of Altman is necessarily prepared using fractal mathematics?

#### FINDINGS OF FACT

FF1 The invention relates to a method of releasing a compound into an intravenous environment (Spec. 1).

FF2 According to the Specification:

The method includes providing a compound releasably captured within a matrix material, the compound being releasable upon receiving an energy input. The method includes placing the matrix material and captured compound in fluid communication with a fluid which flows in a biological space of the biological unit. Energy is provided to the matrix material sufficient to release a portion of the compound, and the compound is released into the biological unit in an irregular pattern.

(*Id.* at 4.)

FF3 The Specification discusses preparing a control signal using fractal mathematics (*id.* at 32-36).

FF4 The Specification teaches that many natural systems exhibit structure characterized by chaotic behavior, and that fractional Brownian motion (fBm) may be used as a model for many random fractals found in nature (*id.* at 32).

FF5 Thus, according to an embodiment of the invention, “the application of energy to the catheter assembly is applied according to a 1-dimensional algorithm to synthesize fBm fractal Brownian motion.” (*Id.* at 33.)

FF6 The Examiner rejects claims 57-59, 62, 64, 105, and 106 under 35 U.S.C. § 102(e) as being anticipated by Altman (Ans. 3).

FF7 The Examiner cites Altman for teaching a method of providing a compound to a system (*id.* at 4).

FF8 As to the control signal, the Examiner finds that Altman teaches a controller that “senses electrical activity of the heart and responds by injecting delivery of the drug or goes into monitoring mode depending on the sensed electrical activity.” (*Id.* (citing Altman, col. 14, ll. 7-47; col. 14, l. 66-col. 15, l. 47).)

FF9 The Examiner finds that the control signal of Altman is prepared by using fractal mathematics. According to the Examiner:

It is being considered that the computer/controller is inherently producing fractal mathematics since fractals are generated by an iterative process - doing the same thing again and again. The computer/controller has this factor built in. Fractals also have the property that when you magnify them they still look much the same. The device of Altman produces the same control signal to release the compound. Further, if fractal mathematics is considered to be calculations based on fractions, any integer is considered to be a fraction or could be represented as a fraction.

(Ans. 7.)

FF10 Specifically, Altman teaches an implantable transient drug delivery catheter, wherein the catheter is implanted into a suitable site so as to deliver antiarrhythmic agents as well as sense electrical activity near the device (Altman, col. 14, l. 66-col. 15, l. 6).

FF11 The catheter of Altman is connected to an external controller and power source (*id.* at col. 15, ll. 6-12). The device senses cardiac activity through the surface of the drug delivery structure, and when the heart experiences an arrhythmic event, “the controller identifies the event and the energy source which delivers the drug to the heart.” (*Id.* at ll. 12-16.)

FF12 The Examiner rejects claim 60 under 35 U.S.C. § 103(a) as being obvious over the combination of Altman and Chupakhin (Ans. 4).

FF13 Chupakhin is relied upon for the limitation of the use of an anesthetic as the therapeutic agent, with the system being a neurological system (*id.* at 4-5).

FF14 The Examiner rejects claim 61 under 35 U.S.C. § 103(a) as being obvious over the combination of Altman and Donatsch (*id.* at 5).

FF15 Donatsch is relied upon for the limitation of the use of a neurotransmitter as the therapeutic agent, with the system being a neurological system (*id.*).

FF16 The Examiner rejects claim 63 under 35 U.S.C. § 103(a) as being obvious over Altman (*id.* at 6).

FF17 The Examiner concludes that it would have been obvious to modify the frequency to about 1Hz as it would be routine optimization (*id.*).

FF18 The Examiner rejects claims 65 and 104 under 35 U.S.C. § 103(a) as being obvious over the combination of Altman and Elinwood, Jr. (*id.*).

FF19 Elinwood, Jr. is relied upon for teaching a programmable controller for a medication system (*id.*).

#### PRINCIPLES OF LAW

It is axiomatic that in order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). Under the principle of inherency, when the prior art reference is silent as to the limitation asserted to be inherent, it need be clear that the missing descriptive matter is necessarily present in the thing

described in the reference, and that it would be so recognized by the ordinary artisan. *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991).

Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. (Citations omitted.) If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

*Id.* at 1269 (quoting *In re Oelich*, 666 F.2d 578, 581 (CCPA 1981)).

## ANALYSIS

Appellant argues that “Altman fails to teach a fractal based control signal.” (App. Br. 3.) According to Appellant, while the Examiner’s position is that “the computer/controller of Altman is inherently producing fractal mathematics since fractals are generated by an iterative process – doing the same thing again and again,” merely “[s]howing that a computer has an iterative process does not teach, necessitate, or inherently include that fractal mathematics are thereby utilized.” (*Id.* at 4.)

We agree with Appellant. Altman does not teach or suggest the use of fractal mathematics to prepare the control signal. Altman only teaches that the controller releases drug when the heart experiences an arrhythmic event (FF11). The Specification clearly differentiates fractal mathematics as a particular mathematical model with distinct algorithms which are not simply iterative (FF 4-5). In addition, while the Examiner asserts that Altman is inherently using fractal mathematics as fractals are generated using an

iterative process, the Examiner has not provided any evidence or scientific reasoning that the ordinary artisan would conclude that any iterative process necessarily uses fractal mathematics.

#### CONCLUSIONS OF LAW

We conclude that the Examiner has not established by a preponderance of the evidence that the control signal of Altman is necessarily prepared using fractal mathematics.

We are thus compelled to reverse the rejection of claims 57-59, 62, 64, 105, and 106 under 35 U.S.C. § 102(e) as being anticipated by Altman. As the remainder of the rejections do not remedy the deficiencies of the anticipation rejection, we are also compelled to reverse the remaining rejections on appeal, that is, the rejection of claim 60 under 35 U.S.C. § 103(a) as being obvious over the combination of Altman and ; the rejection of claim 61 under 35 U.S.C. § 103(a) as being obvious over the combination of Altman and Donatsch; the rejection of claim 63 under 35 U.S.C. § 103(a) as being obvious over Altman; and the rejection of claims 65 and 104 under 35 U.S.C. § 103(a) as being obvious over the combination of Altman and Elinwood, Jr.

REVERSED

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Application 10/045,550

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SUITE 2700  
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